K972918

OCT 27 1997

Apex Medical Products
9911 W. Pico Boulevard, Suite 301
Los Angeles, CA 90035
(800) 683-8673

XI. SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR IDENTIFICATION	Apex Medical Products, L.L.C. 9911 West Pico Blvd., Suite301 Los Angeles, CA 90035
ESTABLISHMENT REGISTRATION NUMBER:	Pending
MANUFACTURER IDENTIFICATION:	Surgical Technology Inc. 292 East Lafayette Road St. Paul, MN 55107
OFFICIAL CONTACT PERSON:	Norman F. Estrin, Ph.D., RAC President Estrin Consulting Group, Inc. 9109 Copenhaver Drive Potomac , MD 20854 Tel. : (301) 279 -2899 Fax : (301) 294-0126
DATE OF PREPARATION OF THIS SUMMARY:	August 6, 1997
TRADE NAME:	RAPID FIRE HAIR IMPLANTER CAROUSEL™
COMMON NAME:	Hair Transplant Facilitator
CLASSIFICATION NAME AND REFERENCE:	Manual Surgical Instrument (21 CFR, Section 878.4800)
PROPOSED REGULATORY CLASS:	Class I
DEVICE PRODUCT CODE:	GAH
PANEL CODE:	80 SU

000113

DESCRIPTION OF DEVICE:

The **RAPID FIRE HAIR IMPLANTER CAROUSEL™ (Carousel)** is a disposable mechanical device designed to facilitate a hair transplant. It consists of a circular Carousel designed to house hair grafts, a sharp end designed to create an opening in the skin of the scalp and a button end that activates the moving parts within the Carousel.

INTENDED USE:

The **RAPID FIRE HAIR IMPLANTER CAROUSEL™** is intended to be used for hair transplantation on the scalp.

INDICATIONS FOR USE:

The **RAPID FIRE HAIR IMPLANTER CAROUSEL™** is indicated where patients require one or more hair grafting sessions during which multiple grafts have to be implanted.

PREDICATE DEVICE:

The **RAPID FIRE HAIR IMPLANTER CAROUSEL™** is substantially equivalent to the Calivitron Hair Transplant System (manufactured by Medicamat, S.A.) and the Padgett Hair Transplant Punch (manufactured by Padgett Instruments).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the **PADGETT** and the **CAROUSEL** are non-powered simple units that use a stainless steel device for graft cutting. The **CAROUSEL** differs from the **PADGETT** in having a carousel feature that facilitates storage of the graft and speeds up the surgical procedure. These differences between these devices do not impact the safety and effectiveness in a significant way except for the improvements relating to the carousel noted above.

The **CALVITRON** also uses a four bladed scalpel device but utilizes a complex electrically powered system to

provide for aspiration, compression and micromotors. The **CAROUSEL** is much simpler in design than the **CALVITRON**. In contrast the 48 kg **CALVITRON**, which lists 11 components to its system, including a control panel, vacuum and compression connectors, sterile arm unit, etc., the **CAROUSEL** is a hand-held unit roughly the size of a ball point pen.

The **CAROUSEL** consists of a stainless steel blade and the body composed of Lustran 348 resin. The predicate devices also have stainless steel blades which act as the patient contacting surfaces.

SUMMARY OF STUDIES:

Performance test results on the **CAROUSEL** including in vitro tests on porcine skin and a test on a human subject, validated its safety and effectiveness. In the *in vitro* study, visual inspection of the biopsy specimens of groups implanted manually and with the Carousel under loop magnification showed no difference in the gross morphology of the implants. In both the test and control groups the implants were positioned identically in the dermis and in both groups the implants appeared intact and undamaged. Histologic evaluation revealed no significant difference between the implanted tissue of both groups with the exception that the hair follicles implanted with the Carousel were at a somewhat more uniform depth within the porcine tissue than those of the control group.

400 grafts were implanted on the right side of a patient's scalp approximately 1 cm behind the right frontal hairline. The left side was implanted manually, using a Nokor needle and manual forceps. There was much less bleeding by the Carousel

method, resulting in a much shorter time needed for graft placement. The post operative wounds showed no difference between those made with the Carousel and those made with the conventional approach. No difference in the rate of growth or the number of hairs was seen when each of the two groups were compared.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 1997

Apex Medical Products, L.L.C
c/o Norman F. Estrin, Ph.D., RAC
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K972918
Trade Name: Rapid Fire Hair Implanter Carousel™
Regulatory Class: I
Product Code: GAH
Dated: August 7, 1997
Received: August 7, 1997

Dear Dr. Estrin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

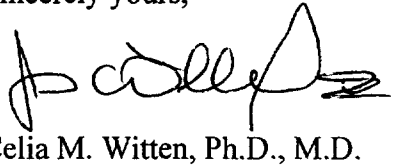
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972918

Device Name: **Rapid Fire Hair Implanter Carousel™**

Indications for Use:

The **Rapid Fire Hair Implanter Carousel™** is to be used for hair transplantation on the scalp. Its use is indicated where patients require one or more hair grafting sessions during which multiple grafts have to be implanted.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972918